K081225

510(k) Summary

PAS•Port™ Proximal Anastomosis System

510(k) Number	
Date Prepared	28 April, 2008
Applicant Information	Cardica, Inc. 900 Saginaw Redwood City, California 94063 Main: 650-364-9975 Fax: 650-364-3134
Contact Person	Iskra Mrakovic Office: 650-331-7153 Fax: 650-364-3134 e-mail: mrakovic@cardica.com
Establishment Registration Number	3004114958
Device Information	Classification Name: Clip, Implantable Regulation Number: 21 CFR §878.4300 Trade Name: Cardica® PAS•Port® Proximal Anastomosis System Common Name: Cardiovascular Surgical Instruments
Legally Marketed Predicate Device(s)	St. Jude Medical Aortic Connector System (#K003446)
Device Description	The Cardica® PAS•Port® Proximal Anastomosis System is a mechanical device used to facilitate an aortic vein graft anastomosis. The connector replaces sutures to create a secure, patent and reproducible anastomosis. The PAS•Port® Proximal Anastomosis System consists of a connector and a delivery system.

Indications for Use	The PAS-Port' System is intended to create the aortic anastomosis of aortic autologous vein grafts.
Comparison to Predicate Device	The PAS•Port® Proximal Anastomosis System is substantially equivalent to the St. Jude Medical Aortic Connector System (#K003446, 21 CFR $878.4300).
Device Testing Results and Conclusion	All necessary *in vitro* and *in vivo* testing has been performed on the PAS-Port' Proximal Anastomosis System and its packaging to ensure substantial equivalence to the predicate device, and to ensure the safety and effectiveness of the device.
Technological Characteristics	See Device Description above.
Substantial Equivalence Summary	Both, the Cardica® PAS-Port' Proximal Anastomosis System and the St. Jude Aortic Connector System are intended for creation of the aortic anastomoses made of aortic autologous vein grafts. Both devices include a metal implant and a delivery system. With both devices, a graft vessel is loaded onto an implant and the delivery device is used to form the implant into a circular grommet-like structure that seals the vein graft to the aorta. The primary difference between the two devices is the material used for the implant. The PAS-Port' Proximal Anastomosis System implant is made of a medical grade 316L Stainless Steel whereas the St. Jude Symmetry device is made from nitinol, i.e., a nickel-titanium alloy.
Conclusions	This Traditional 510(k) Premarket Notification submission has demonstrated Substantial Equivalence with the St. Jude Aortic Connector System (#K003446) as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2008

Cardica, Inc.
c/o Ms. Iskra Mrakovic
VP, Clinical Affairs
Manager, Regulatory Affairs
900 Saginaw Drive
Redwood City, CA 94063

Re: K081225
PAS-Port Proximal Anastomosis System
Regulation Number: 878.4300
Regulation Name: Implantable Clip
Regulatory Class: II (two)
Product Code: FZP
Dated: August 15, 2008
Received: August 18, 2008

Dear Ms. Mrakovic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: (if known)	K081225
Device Name:	Cardica® PAS•Port® Proximal Anastomosis System
Indications for Use:	The PAS•Port® System is intended to create the aortic anastomosis of aortic autologous vein grafts.

Prescription Use ___X___ (Part 21 CFR§801.109)

OR Over-The-Counter Use _____ (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vinci

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K081225